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K113129

HEIDELBERG ENGINEERING

510(k) Summary of Safety and Effectiveness

Manufacturer and Submitter

Company Name:	Heidelberg Engineering GmbH
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Contact Person:	Dr. Gerhard Zinser
Date Summary Prepared:	September 13, 2011

Device

Trade/Device Name:	Spectralis Anterior Segment Module
Common/Usual Name:	Optical Coherence Tomograph
Classification Name:	Ophthalmoscope, AC-powered
Regulation Number:	21 CFR 886.1570
Product Code:	OBO, MYC
Classification Panel:	Ophthalmic
Classification:	Class II

Substantial Equivalence

The Heidelberg Spectralis with Anterior Segment Module is substantially equivalent to the Optovue RTVue 100/CA (K071250), which is technologically similar devices for anterior segment imaging. A second predicate device is chosen, the Heidelberg Spectralis HRA+OCT (K101223) because it is the "parent" device to the Spectralis ASM.

Device Description

The Spectralis Anterior Segment Module (Spectralis ASM) is an accessory to the Spectralis HRA+OCT device cleared under K101223. The Spectralis HRA+OCT is a diagnostic device for imaging the human eye and for aiding in the assessment and management of various diseases of the posterior segment of the eye. Addition of the Spectralis ASM provides the user the additional ability to image and examine the anterior segment of the eye using simultaneous OCT and infra-red reflectance imaging with OCT B-scan lengths of 8 mm, 11 mm, and 16 mm. Available OCT scan patterns are single line scans and volume scans.

Intended Use/Indications for Use

The Spectralis Anterior Segment Module is an accessory to the Spectralis HRA+OCT, and is indicated for imaging the anterior segment of the eye.

Substantial Equivalence Analysis

Analysis of the intended use of the predicate devices and the Spectralis ASM has led to the conclusion of substantial equivalence. The new device is similar to the predicate device in the use and ability to image and view the anterior segment of the eye. The Intended Use of the new device does not include the measurement of ocular structures of the eye, and this difference does not affect the use of the Spectralis ASM for viewing the same ocular structures as the predicate.

Spectralis ASM has been demonstrated to perform as intended and has been shown to be substantially equivalent to the RTVue predicate device for viewing ocular structures of the eye. The technology characteristics of the new device when used with the Spectralis HRA+OCT (parent product) are similar to the RTVue predicate in design, materials and energy source, as both the new device and the RTVue auxiliary lens adapter are anterior lens accessories that are used together with the parent product to view the anterior segment of the eye.

Performance – Nonclinical

Bench Testing

The Spectralis HRA+OCT has been tested according to IEC 60601-1, IEC 60601-1-2, and IEC 60601-1-4 and was found to meet all requirements. The Spectralis with Anterior Segment Module is a laser product of Class 1 according to 21 CFR §1040.10 and complies with IEC 60825-1.

Studies to Demonstrate Equivalence in Viewing the Anterior Segment

Side-by-side images of the anterior segment of the eye were compared between the Spectralis ASM and the predicate. Images from both eyes of 29 subjects (healthy eyes and eyes with pathology) were compared by an ophthalmologist using Spectralis ASM and RTVue, and equivalence between the images was concluded.

Conclusions

This study confirmed the ability of the Spectralis ASM to image and view the anterior segment, and the substantial equivalence of Spectralis ASM to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Heidelberg Engineering GmbH
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Re: K113129
Trade/Device Name: Spectralis Anterior Segment Module (Spectralis ASM)
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: OBO, MYC
Dated: October 21, 2011
Received: October 24, 2011

Dear Mr. Sammons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113129

Indications for Use

510(k) Number (if known): K113129

Device Name: Spectralis Anterior Segment Module

Indications For Use:

The Spectralis Anterior Segment Module is an accessory to the Spectralis HRA+OCT, and is indicated for imaging the anterior segment of the eye.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K113129